

EXHIBIT 1

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION)	CASE NO. 1:17-MD-2804
)	
)	SPECIAL MASTER COHEN
THIS DOCUMENT RELATES TO:)	
"Track One Cases")	
)	
)	<u>DISCOVERY RULING NO. 2</u>
)	

The undersigned has received numerous emails and letters from plaintiffs and defendants raising various discovery issues. Having reviewed carefully the parties' positions, the Special Master now enters the following discovery rulings.

Scope of Products Subject to Discovery

Plaintiffs have requested discovery related to a wide array of opioids that are manufactured, sold, or distributed by the defendants, including branded products, generic products, and lower-strength products that have been sold "without problem" for decades. The *distributor* defendants have not objected to these requests – the distributors have agreed to produce discovery for all opioid products requested by plaintiffs. To various degrees, however, the *manufacturer* defendants do object to the breadth of the plaintiffs' requests. For example:

- Teva has no objection to plaintiffs' requests based on identity of the opioid product; thus, Teva is producing discovery related to all opioids, including unbranded and generic products.

- Purdue is willing to produce documents related to three of its branded opioid products (Oxycontin, Butrans, and Hyslinga ER), but objects to discovery of documents related to (a) any other branded opioid product (e.g. Targiniq ER), and (b) any unbranded or generic opioid product.
- Janssen is willing to produce documents related to three of its newer branded opioid products (Duragesic, Nucynta, and Nucynta ER), but objects to discovery of documents related to, among others, two branded, decades-old, combination opioid products (41-year-old Tylenol [acetaminophen] with codeine; and discontinued-in-2014, 32-year-old Tylox [acetaminophen with oxycodone]).

At this juncture, plaintiffs are in dispute on this issue with Endo, Mallinckrodt, Allergan, Janssen, and Purdue.

The main reason offered by defendants to support their objections is that plaintiffs' complaints do not sufficiently allege theories of liability based on the manufacture, sale, or distribution of *generic* drugs. This is simply untenable. Plaintiffs' complaints certainly focus upon branded drugs, such as Oxycontin; but the allegations clearly also support claims premised on the manufacture, sale, and distribution of generic drugs. *See, e.g., City of Cleveland v. Purdue Pharma*, case no. 18-OP-45132, second amended complaint ¶5 (docket no. 508) ("*Cleveland Complaint*") (attributing the huge number of deaths caused by opioid overdose to drugs including "brand-name prescription medications such as OxyContin, Opana ER, Vicodin, Subsys, and Duragesic, as well as generics like oxycodone, hydrocodone, and fentanyl"); *id.* at ¶45, 49, 65, 78, 87, 824 (referring to individual generic drugs produced by each manufacturer defendant).

A second reason defendants offer to support their objections is that some of the drugs at issue

are low-potency products that were launched decades before there was any “opioid crisis” (which plaintiffs allege began in the “late 1990s;”¹ therefore, these drugs are at best barely relevant to plaintiffs’ claims and the burden of production exceeds its likely benefit. The Special Master concludes this argument is well-taken. Tylenol with codeine has been available in the United States since the 1970s, and is listed by the FDA as a Schedule III drug – meaning it has a lower potential for abuse than substances in Schedule II (such as hydromorphone, oxycodone, fentanyl, and morphine), which are at the alleged root of the “opioid crisis.” Tylenol with codeine is clearly peripheral to plaintiffs’ claims.

Accordingly, the Special Master **RULES** as follows. Defendants shall produce discovery related to all opioid products that are or ever were classified as Schedule II under the Controlled Substances Act. This includes branded, unbranded, and generic drugs. If a branded drug was launched before 1995, then defendants need to produce documents related to that drug, and its non-branded and generic equivalents, only if the documents were created on or after January 1, 1995.

Geographic Scope of Discovery

The plaintiffs in the Track One cases are all located in the Northern District of Ohio, but Plaintiffs’ discovery requests are largely national in scope. With regard to certain categories of documents, most defendants do not lodge objections based on geographic scope. Thus, for example, most of the manufacturer defendants have agreed to produce nationwide information on their marketing, advocacy, and regulatory activities. But several defendants object to production of other types of information outside of Ohio – for example, sales information for each customer pharmacy,

¹ See, e.g., *Cleveland Complaint* ¶¶4-7, 690-91, & 789.

notes on sales calls, compensation of sales representatives, and so on. Other defendants have taken a more surgical approach: manufacturer Mallinckrodt, for example, has agreed to provide “documents relating to diversion” on a national basis, but “documents that pertain to marketing” only in sales districts encompassing Ohio and its border states of Michigan, Indiana, Kentucky, West Virginia, and Pennsylvania. The bases for defendants’ geographic scope objections are burden and relevance.

The Special Master now **RULES** as follows. Defendants must produce on a national basis documents related to marketing and promotion, brand planning and strategy, sales training and sales bulletins, prescriber educational materials, distribution monitoring, advocacy groups, speakers bureau programs, continuing medical education, diversion, suspicious order reports, adverse event reports, and regulatory activity.² The defendants’ policies and actions regarding all of these subjects are (and were) primarily centralized and over-arching, applying broadly to their opioid products. This discovery is referred to below as Category One Discovery.

The ruling above is relatively easy; the harder question is the extent to which defendants must produce documents related to decentralized, customer-specific materials, such as sales call notes and transactional data. (This discovery is referred to below as Category Two Discovery.) As noted earlier, most defendants seek to limit geographic production of these materials to Ohio, where plaintiffs in the Track One cases are located. In response, plaintiffs argue this information should be produced more broadly – at least regionally, if not nationally – as materials connected to locations outside of Ohio are likely to reveal information relevant to the Ohio plaintiffs’ claims. For

² This list is illustrative, not exhaustive. The Special Master has carefully considered whether each of the topics in this list should be included.

example, plaintiffs allege there is “abundant evidence . . . establish[ing] that prescription opioids migrated between cities, counties, and states, including into Ohio from West Virginia, Kentucky, Illinois, Georgia, and Florida.” *Cleveland Complaint* ¶633. The Special Master agrees that tracing opioid migration to Ohio from other locations, especially high-supply areas, is relevant to plaintiffs’ claims.

The Special Master concludes it is appropriate to enter a compromise ruling: defendants shall produce customer-specific information for the States of Ohio, Pennsylvania, West Virginia, Kentucky, Illinois, Georgia, and Florida. This restriction will provide plaintiffs with sufficient discovery to test their “migration” theory and pursue their claims, while limiting the burden on defendants. To the extent defendants must produce this discovery in stages, production of Ohio information shall occur first.

Scope of Prior Productions

Numerous defendants have produced documents in connection with other, earlier litigation matters or governmental investigations. In regard to these “prior productions,” the Court ordered as follows in CMO-1:

all Defendants shall review documents previously produced pursuant to any civil investigation, litigation, and/or administrative action by federal (including Congressional), state, or local government entities involving the marketing or distribution of opioids and shall produce to the PEC non-privileged documents relevant to the claims in this MDL proceeding.

Docket no. 232 at 15, ¶9.k.ii. Initially, some defendants agreed to produce only those prior productions that had occurred after a date-certain, such as January 1, 2006. Those defendants have correctly abandoned that position. But some defendants now assert they do not have to produce

certain prior productions for other reasons – for example, because a prior production in patent litigation did not “involv[e] the marketing or distribution of opioids,” or because the prior production was made in *private* civil litigation as opposed to litigation with a governmental entity.

The Special Master now **RULES** as follows. The above-quoted language in CMO-1 was meant to be comprehensive. Defendants’ objection that they are not obligated to produce in the MDL prior productions made in private (“non-governmental”) litigation is not well-taken. If a defendant produced discovery in *any* prior litigation that involved the marketing or distribution of opioids, that discovery must be produced in the MDL.³ That said, the Special Master agrees that defendants need not produce discovery of prior productions made in cases, such as patent litigation, that only tangentially addressed marketing and distribution of opioids.

The Special Master adds that defendants must produce prior productions made in personal injury cases, because those productions are highly likely to include materials relevant to distribution and marketing of opioids. More specifically, the Special Master notes that MDL lead plaintiff counsel Paul Hanly has engaged in prior litigation against manufacturer Purdue involving claims that Purdue’s sale and marketing of Oxycontin led to personal injuries to hundreds of plaintiffs.

³ Defendants apparently read the language in CMO-1 to mean they are only required to produce in the MDL prior productions made in “litigation . . . by federal (including Congressional), state, or local government entities,” and not by private entities. The underlined clause, however, was meant to make fully *expansive* the requirement relative to administrative actions, not to *restrict* the requirement relative to litigation or investigations.

Purdue's prior discovery productions in those cases is relevant and discoverable in the MDL.⁴ To lower Purdue's discovery burden, rather than requiring Purdue to re-produce its prior productions made to Hanly's firm, these prior productions "shall be deemed produced to all Plaintiffs in MDL 2804 and shall be made immediately available to the PEC by any parties or counsel in possession of same, at no cost to the party or counsel in possession." See docket no. 232 at 15, ¶9.k.i (CMO-1) (taking this approach with prior productions made in *City of Chicago v. Purdue Pharma L.P.*, case no. 17-OP-45169).

List of Prior Productions

The Special Master earlier directed each defendant to produce to plaintiffs a "list of all prior productions in any civil investigation, litigation, and/or administrative action involving the marketing or distribution of opioids," so that the parties and the Court could "understand precisely what is the universe of prior productions at issue." Email to counsel, June 13, 2018. 6:06 pm. However, many of those defendants that responded – some still have not – did not include in their lists prior productions made in private, non-governmental civil litigations. The Special Master now **ORDERS** every defendant to produce to plaintiffs, on or before July 10, 2018, a list of every prior production in any earlier litigation, investigation, or administrative action that touches upon the marketing or distribution of opioids, *without exception*. This separate requirement is meant only to

⁴ Mr. Hanly has stated repeatedly that Purdue's earlier discovery in his personal injury cases is clearly relevant to the claims in the MDL, and Purdue has not contested that assertion – although it has withheld permission for Mr. Hanly to share his discovery in the MDL. This is unacceptable. It would be very odd and unsound for two different MDL lead plaintiffs' counsel – say, Mr. Hanly and Mr. Farrell – to attend a deposition of Purdue where Mr. Hanly is aware of relevant documents (but cannot use them), and Mr. Farrell is not.

obligate each defendant to produce a *list*, not to produce each and every single one of those prior productions. Among other reasons, this list is necessary for the plaintiffs and the Court to engage in the mechanism set out at CMO-1, ¶9.k.iii (“to the extent the PEC believes there are other documents that were produced by a Defendant in another proceeding that are discoverable in this proceeding, the PEC shall notify the Defendant and identify the specific document(s) and basis for requesting production, and the parties shall meet and confer to attempt to resolve the issue”).

Temporal Scope of Discovery

Plaintiffs’ discovery requests are made without any time limit, and plaintiffs generally seek documents dating back to 1995 or even earlier. Defendants object and seek to limit their responses to various other, later dates. For example, distributors McKesson, Amerisource, and Cardinal have each agreed to provide documents from January 1, 2013 forward, but not earlier; manufacturer defendant Teva has agreed to provide documents from January 1, 2006 forward, as well as certain categories of documents that pre-date 2006; and manufacturer defendant Endo has agreed to provide documents with a begin-date of two years prior to the launch of its opioid product Opana ER. The reasons distributors offer for limiting the begin-dates of their discovery production include: (a) statutes of limitations, (b) when their opioid products were launched, and (c) general relevance and burden.

The question of temporal scope is the most difficult of the issues addressed in this *Discovery Ruling*. Obviously, the earlier the cut-off date for document production, the more burdensome is the discovery request on defendants, and potentially the less relevant. Still, the Special Master rejects the defendants’ contentions that the cut-off date should be set by strict reference to statutes

of limitations. See *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 352 (1978) (“it is proper to deny discovery of . . . events that occurred before an applicable limitations period, unless the information sought is otherwise relevant to issues in the case”); *Ray v. Waste Mgmt. of Kentucky, LLC*, 2010 WL 11545747 at *1 (W.D. Ky. Dec. 15, 2010) (denying a motion to limit discovery to the limitations period, because discovery into earlier events could lead to relevant and admissible evidence). Moreover, it appears the statute of limitations for plaintiffs’ claims of public nuisance may be equitably tolled. See *The Little Miami RR Co. v. Comm’rs of Greene Cty.*, 1877 WL 31 at *6 (Ohio Dec. 1, 1877) (“no length of time can legalize a public nuisance”); cf. *State v. Swartz*, 88 Ohio St. 3d 131, 134 (2000) (in the case of criminal nuisance, “a continuing nuisance can constitute a continuing course of conduct, thus tolling the limitations period”).

With regard to relevance, plaintiffs argue convincingly that “baseline evidence” of what the opioid marketplace looked like before defendants undertook their allegedly fraudulent marketing activities, and before defendants allegedly purposely failed to report Suspicious Orders, is highly relevant. The amount and degree of “unnecessary prescriptions” and the extent of the “inappropriate increase” of opioid distribution must be measured against a time before the allegedly wrongful activity began; that is, the scope of the “opioid crisis” can only be assessed against pre-crisis conditions. Indeed, the U.S. Drug Enforcement Agency describes Suspicious Orders as “orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” 21 C.F.R. §1301.74(b). This language necessitates comparisons with “normal” and “usual” circumstances. Plaintiffs provide data showing opioid prescriptions and distributions began to increase dramatically in 1995, which is when Purdue launched Oxycontin. In sum, the baseline level of opioid prescriptions and distributions, which existed at that juncture, is highly relevant.

Ultimately, the dispute over the temporal scope of discovery requires a balancing of burden, relevance, and need. The Special Master has undertaken that calculation with an eye toward providing plaintiffs with evidence they need but no more than that, and with as little burden on defendants as this measure allows. This requires imposition of different, tailored cut-off dates for discovery of different categories of information from different defendants. A single cut-off date for all discovery would be both over- and under-inclusive. Accordingly, the Special Master now **RULES** as follows.

Manufacturer Defendants

Except as stated in the next paragraph, the manufacturer defendants shall produce Category One Discovery and Category Two Discovery with a cut-off date of one year prior to the launch date of the opioid product in question. Thus, for example, Purdue must produce Categories One and Two Discovery related to Oxycontin going back to the date one year before it began selling Oxycontin; Purdue must produce Categories One and Two Discovery related to Hyslinga ER going back to the date one year before it began selling Hyslinga ER; and Mallinckrodt must produce Categories One and Two discovery related to Xartemis XR going back to the date one year before it began selling Xartemis XR. These dates are very different, as they are individualized to each drug.⁵ Further, each manufacturer defendant must produce Categories One and Two discovery for generic opioids with a cut-off date of one year before it first sold that generic product.

Further, the manufacturer defendants shall produce transactional data (which is otherwise

⁵ Purdue's Oxycontin was approved by the FDA in December of 1995, while Purdue's Hyslinga ER and Mallinckrodt's Xartemis XR were approved in 2014. The Special Master adds here that this "one year" requirement applies regardless of when the defendant acquired rights to the drug.

in Category Two) and Suspicious Order Reports (which is otherwise in Category One) with a cut-off date of January 1, 1996.

Distributor Defendants

The distributor defendants shall produce transactional data and Suspicious Order Reports with a cut-off date of January 1, 1996. The discovery cut-off for all other discovery is January 1, 2006.

Discovery of Prior Transcripts

Although this topic was disputed, the parties' most recent reports to the Special Master reveal there are no remaining disagreements regarding production of transcripts of testimony taken in prior opioid-related litigation or investigations.

Definition of "Marketing Activities"

Earlier, some of the defendants objected to the definition of "marketing activities" that plaintiffs included in their discovery requests. It appears most of the defendants have resolved their disputes with plaintiffs regarding this issue, but some defendants (e.g. Mallinckrodt) have lingering disagreements. The specific language at issue is as follows:

"Marketing" refers to the action or business of promoting, selling, or providing information about Opioids or Opioid Products. "Marketing" includes both branded and unbranded Communications; branded and unbranded informational or educational programs; detailing by sales representatives (including electronic detailing); continuing medical education; publication of scientific medical or marketing articles, Scientific Research, studies or reports; websites (whether branded or unbranded); video or other visual media; sales blasts, messages, or other means used to sell or promote Opioids or Opioid Products for sale or distribution.

Requests for Production at 3.

The Special Master simply observes that this definition in the abstract does not appear to be over-broad or to require production by defendants of irrelevant information. The Special Master directs those parties who continue to have disagreements over the definition of marketing to meet and confer again while taking this observation into account.

Different Agreements

The Special Master is aware that certain defendants may have reached agreements with plaintiffs on certain issues that are different from the requirements stated above. For example, this *Discovery Ruling* directs the manufacturer defendants to produce relevant documents with a cut-off date of one year prior to the launch date of their opioid products, but Janssen earlier agreed to produce documents going back two-and-a-half years before its launch of Nucynta. The parties are free, but not required, to honor these prior agreements, and are free to negotiate different agreements going forward from the requirements set out herein. But the Special Master hereby imposes consistent standardized rulings for all parties, so that there will be clarity going forward.

Pharmacies

The discussion above addresses discovery disputes plaintiffs have had with the manufacturer and distributor defendants. The Special Master has not received position papers on these topics from the retail pharmacy defendants, as their meet-and-confers with plaintiffs are ongoing. Nonetheless, the Special Master expects the pharmacy defendants will adhere to the rulings set out above and will not bring a similar dispute to the undersigned unless there is very good cause for a different

outcome.

Other Issues

The Special Master is aware there are other discovery disputes brewing, including a complete absence of scheduling of 30(b)(6) depositions. The parties are **ORDERED** to: (1) submit on or before July 6, 2018 an agreed schedule for at least some 30(b)(6) depositions, or risk sanctions; and (2) continue to meet and confer on all other outstanding disputes.

RESPECTFULLY SUBMITTED,

/s/ David R. Cohen

David R. Cohen

Special Master

Dated: June 30, 2018